

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

JULIE BRASHEAR,

Plaintiff,

v.

PACIRA PHARMACEUTICALS,
INC., *et al.*,

Defendants.

Case No. 1:21-cv-700

JUDGE DOUGLAS R. COLE

OPINION AND ORDER

After a surgery, Julie Brashear's doctors gave her an anesthetic called Exparel to manage her pain. But she thinks the drug made her problems worse. She says it partially paralyzed her diaphragm, causing long-term breathing trouble. Pacira Pharmaceuticals made Exparel.

Brashear further believes that Pacira knew Exparel carried a high risk of injury but failed to warn her or her doctors. She sued. Pacira now moves to dismiss, arguing Brashear has failed to state a claim. The Court agrees in part.

Because federal regulations preempt certain state law product liability claims, the Court **GRANTS** Pacira's Motion to Dismiss (Doc. 5) as to Brashear's design defect, failure-to-warn, and punitive damages claims and **DISMISSES** those claims **WITH PREJUDICE**. The Court further **GRANTS** Pacira's Motion to Dismiss (Doc. 5) as to Brashear's false marketing and supplier liability claims and **DISMISSES** those claims **WITHOUT PREJUDICE**.

Separately, the Court **ORDERS** Brashear to **SHOW CAUSE**, no later than May 12, 2023, why the Court should not dismiss this action as against Pacira Pharmaceuticals International, Inc. and Pacira Biosciences, Inc. without prejudice for failure to effect service, or in the alternative why the Court should allow an extension of time to for Brashear to complete service on these two defendants.

BACKGROUND

When deciding a motion to dismiss for failure to state a claim, the Court assumes that the complaint's factual allegations are true. Thus, the Court largely relies on the facts in Brashear's Complaint for this decision, but with the caveat that these facts are not yet established and may never be. *Koren v. Neil*, No. 1:21-CV-9, 2022 WL 974340, at *1 (S.D. Ohio Mar. 31, 2022).

Brashear had her left shoulder surgically replaced. (Compl., Doc. 1, #3). After the surgery, her doctors injected Exparel to ease her pain. (*Id.*). She alleges the injection paralyzed the left side of her diaphragm. (*Id.*). Later, she developed pneumonia and other long-term respiratory issues. (*Id.*). She thinks Pacira defectively designed Exparel and did not communicate the risks associated with those defects to her or her doctors, ultimately leading to her injury. (*Id.* at #3–4). So she sued.

Brashear brought claims against three defendants: Pacira Pharmaceuticals, Inc., Pacira Pharmaceuticals International Inc., and Pacira Biosciences, Inc. (*Id.* at #1). To date, Brashear has only served Pacira Pharmaceuticals, Inc—referred to simply as “Pacira” throughout this Opinion. Brashear's Complaint contains five

claims, all under Ohio's Product Liability Act. (*Id.* at #4, 5, 6). First, she claims Defendants defectively designed Exparel. (*Id.* at #4). Second, she claims Defendants knew that an Exparel injection carried a risk of diaphragmatic injury yet failed to warn her of this risk. (*Id.* at #4–5). Third, she claims Defendants falsely marketed Exparel as a safe and effective medication for post-operative pain management, but it was not. (*Id.* at #5). Fourth, she claims that Defendants bear supplier liability for sending Exparel to market and selling it to physicians. (*Id.*). Finally, she claims that Defendants acted maliciously by consciously disregarding her health and safety, entitling her to punitive damages. (*Id.* at #6).

Pacira moved to dismiss her Complaint, arguing that FDA regulations preempt each of her state-law claims. (Doc. 5, #33). Brashear argues otherwise. (Doc. 15). Pacira has since replied (Doc. 17), and the Motion is ripe for review.

LAW AND ANALYSIS

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a “complaint must present sufficient facts to ‘state a claim to relief that is plausible on its face.’” *Robbins v. New Cingular Wireless PCS, LLC*, 854 F.3d 315, 319 (6th Cir. 2017) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). In making that determination, the Court “construe[s] the complaint in the light most favorable to the plaintiff.” *Bassett v. Nat’l Collegiate Athletic Ass’n*, 528 F.3d 426, 430 (6th Cir. 2008) (quoting *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007)) (internal quotation marks omitted). But that grace only extends so far. A complaint will not meet this standard when it

is wholly comprised of state-law claims preempted by federal law. *See, e.g., Robbins*, 854 F.3d at 319.

The United States Constitution makes federal law supreme. Accordingly, “state laws that conflict with federal law are without effect.” *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 479–80 (2013) (citations and internal quotation marks omitted). Federal law can expressly or impliedly preempt state law. *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 293 (6th Cir. 2015). Express preemption arises when Congress states in a federal statute an intent to displace state law. *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). Federal law impliedly preempts state law, on the other hand, in at least two circumstances: “when Congress intends federal law to occupy the field, or when state law conflicts with a federal statute.” *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000) (cleaned up). Courts generally refer to the latter of these two as “conflict preemption.”

Conflict preemption can arise in one of two ways: (1) “when it is impossible for a private party to comply with both state and federal law,” or (2) when the state law is “an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Yates*, 808 F.3d at 294 (cleaned up) (quoting *Crosby*, 530 U.S. at 372–73). Here, Pacira argues that federal law preempts Brashear’s state law product liability claims based on the impossibility ground of conflict preemption. Because the parties only discuss impossibility preemption, the Court likewise limits its analysis to that theory.

Under the impossibility analysis, the question is whether Pacira “could independently do under federal law” what Brashear’s state-law claims would require of it.¹ *See id.* at 295 (quoting *Mensing*, 564 U.S. at 620). To make that determination, the Court starts by identifying what duty Brashear alleges Pacira had under Ohio law in developing Exparel with respect to each of Brashear’s claims. *Id.* at 297. Then, the Court determines whether any federal law prevented Pacira from performing that purported duty. *Id.* at 298. The Court analyzes Brashear’s five claims in the order they appear in her Complaint.

A. FDA Regulations Preempt Brashear’s Design Defect Claim Under Ohio Law.

Brashear says that Pacira defectively designed Exparel, leading to her injury. (Doc. 1, #4). Under Ohio law, a product is defectively designed or formulated if, when it left the control of its manufacturer, the foreseeable risks associated with its design or formulation outweighed the benefits of that design or formulation. Ohio Rev. Code § 2307.75(A). In other words, Brashear claims Ohio law imposed on Pacira a duty to make Exparel in a way that ensured any risks of using it for post-surgical pain relief did not outweigh its pain-relieving benefits. In doing so, Brashear has not specifically alleged any alternative way Pacira could have designed Exparel to mitigate the risks

¹ Brashear argues that the Court should not consider preemption at the motion-to-dismiss stage. But this Court has done so many times. *See, e.g., Heliene, Inc. v. Total Quality Logistics, LLC*, No. 1:18-cv-799, 2019 WL 4737753, at *3 (S.D. Ohio Sept. 27, 2019) (granting defendant’s motion to dismiss based on federal law preempting plaintiff’s fraud claim); *Cincom Sys., Inc. v. LabWare, Inc.*, No. 1:18-cv-83, 2021 WL 675437, at *5 (S.D. Ohio Feb. 22, 2021) (granting defendant’s motion to dismiss on the ground that the plaintiff’s common-law claims were preempted by Ohio law).

she claims existed. (*See* Doc. 1, #4). Essentially, Brashear just asserts that Pacira should have made Exparel differently, without suggesting how. But even assuming that is enough to make out a claim under state law, the problem is that, under federal law, Pacira could not have made any such changes.

Once the FDA approves a drug, a manufacturer cannot change the drug’s “qualitative or quantitative formulation of the drug product.” *Yates*, 808 F.3d at 298 (quoting 21 C.F.R. § 314.70(b)(2)(i)). The FDA considers such a change to be a “major change” that requires prior approval before a manufacturer can distribute the altered drug.² *Id.* The FDA in 2018 approved Exparel for use as a safe and effective nerve block for pain relief after shoulder surgeries. (Doc. 5, #39). It was at that point that Pacira could no longer change Exparel’s formulation. If, after receiving that approval from the FDA, Pacira were to redesign Exparel (as Brashear suggests it needed to)—either by changing the recommended dosage or by modifying the composition of the drug itself—Pacira would have been making a prohibited “major change.” Thus, as the Sixth Circuit has made clear, Brashear’s post-approval design defect claim is “preempted by federal law.” *Yates*, 808 F.3d at 298.

Separately, Brashear seems to allege that Pacira could have just designed its drug differently in the first place—that is, *before* the drug received FDA approval. (Doc. 1, #3–4). But the *Yates* court addressed that notion, as well. *Yates*, 808 F.3d at 299. According to the Sixth Circuit, any such “pre-approval” duty is “too attenuated,”

² Moderate or minor changes have different notice requirements. *Yates*, 808 F.3d at 298. But Brashear’s allegations concern Exparel’s chemical ingredients, and any change to that chemical makeup would be “major.” *See id.*

because it requires assuming the FDA would have approved the safer design. *Id.* The same logic applies here. To the extent that a pre-approval duty exists, Pacira could not have complied with it without still getting FDA approval through the standard new drug application process. *See id.* at 300; 21 U.S.C. § 355(a) (describing the procedure for new drug applications). Brashear has not specifically alleged facts that support the hypothetical scenario in which the FDA would have approved a differently formulated Exparel.

In sum, Brashear’s state law design defect claim presumes that Pacira could have just changed Exparel’s formulation. This Court finds that it would have been a violation of FDA regulations for Pacira to make any changes to Exparel’s design because it had already been approved by the FDA. Accordingly, federal law preempts Brashear’s design defect claim.

B. FDA Regulations Preempt Brashear’s Failure-To-Warn Claim.

Brashear separately advances a failure-to-warn claim, saying she was injured because Pacira did not warn her or her doctors about Exparel’s risks. (Doc. 1, #5). Under Ohio law, a manufacturer has a duty to provide adequate warning of any reasonably foreseeable risks associated with its product. Ohio Rev. Code § 2307.76. The Exparel that Brashear received included labeling that warned of the risk of “persistent or permanent” paralysis. (Doc. 5, #39). Brashear does not say what other warning Pacira should have provided but mentions several times the term “diaphragmatic paralysis.” (Doc. 1, #3, 4). This suggests she thinks Pacira should

have changed Exparel's warning label to include the more specific risk of paralysis of the diaphragm.

But for the same reason that Pacira could not have changed Exparel's design or formulation after the FDA had approved the drug for use, Pacira could not have changed its warning label—the FDA had already approved it in 2018. (Doc. #5, 38). And once a drug has been approved, companies like Pacira can only modify their drug's labeling in one of two ways: (1) by submitting a supplement to the FDA and waiting for approval or (2) through the “Changes Being Effectuated” (“CBE”) process. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 581 (6th Cir. 2013) (interpreting FDA labeling regulations codified at 21 C.F.R. § 314.70).

Since the FDA approved Exparel in 2018, Pacira has warned of Exparel's risk of paralysis under the “Warnings and Precautions” part of the Full Prescribing Information section. (Doc. #5, 39–40). FDA regulations say that any change to this section of an approved drug also requires a change to the “Recent Major Changes” part listed in the drug's Highlights section. *See, e.g.*, 21 C.F.R. §§ 201.57(a)(5), (c)(1)–(3), (c)(5)–(6); 21 C.F.R. § 314.70(b)(2)(v)(C). And any change to the Highlights section requires prior FDA approval of a supplement to the drug's labeling before distribution can occur. *Fulgenzi*, 711 F.3d at 581. Pacira could not have independently added language to Exparel's warning label to specify the risk of diaphragm paralysis because it would have needed the FDA's advanced approval. Thus, federal law preempts Brashear's failure-to-warn claim.

Nor does the availability of the CBE process change this result. The CBE process allows manufacturers to independently “add or strengthen” a drug’s warning label *without* waiting for preapproval by the FDA. *Mensing*, 564 U.S. at 614. But a drug manufacturer can only use the CBE process to reflect “newly acquired” safety information. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019). Additionally, this new information must show “evidence of a causal association” between the drug and the risk of injury. *Id.* Newly acquired information includes data, reports of adverse events, or new analyses not previously submitted to the FDA. *See* 21 C.F.R. § 314.3(b).

While the Supreme Court and the Sixth Court have not explicitly discussed who bears the burden of showing the newly acquired information, other circuits have. Those courts say the plaintiff must plausibly allege information showing that a manufacturer would have been able to use the CBE process to change its drug labeling. *See, e.g., Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708–09 (2d Cir. 2019) (ruling that “conclusory and vague allegations” cannot plausibly show the existence of newly acquired information); *In re Celexa and Lexapro Marketing & Sales Practices Litig.*, 779 F.3d 34, 42–43 (1st Cir. 2015) (dismissing plaintiff’s failure-to-warn claims on preemption grounds because plaintiff did not allege any information that would have enabled the manufacturer to use the CBE process). This Court agrees.

Once the FDA has approved a label, the presumption is that the FDA conducted the necessary vetting and research to confirm that the label accurately

communicates the risks with using the drug. *In re Darvocet, Darvon, and Propoxyphene Products Liability Litigation*, 756 F.3d 917, 922 (6th Cir. 2014) (explaining that the FDA can only approve a drug when it determines the drug is “safe for use” as prescribed in the “proposed labeling thereof”). To rebut this weighty presumption, it makes sense to require the party disputing the efficacy of a drug’s warning label to show exactly *why* the warning was inadequate and presented a risk of harm. But if a plaintiff *does* point to newly acquired information that would have allowed a manufacturer to use the CBE process to make a label change, courts will only find impossibility preemption where there is “clear evidence” the FDA would not have approved the warning required by state law. *See Albrecht*, 139 S. Ct. at 1676.

Brashear has not met this standard here. (Doc. 1, #4, 5). Rather, Brashear offers only conclusory allegations that cannot defeat a motion to dismiss. *See, e.g., Ashcroft*, 556 U.S. 662; *Twombly*, 550 U.S. 555.

Because Brashear has not identified any newly acquired safety information that would have allowed Pacira to initiate the CBE process, Pacira could not have changed Exparel’s warning label without first getting FDA approval. Thus, conflict preemption prevents Brashear from advancing her failure-to-warn claim.

C. Brashear Has Not Plausibly Alleged A False Marketing Claim Because She Did Not Identify A Statement About Exparel On Which She Relied Outside The Label.

Brashear says that Pacira improperly marketed Exparel as safe and effective for use as a post-surgery pain killer. (Doc. 1, #5). To prevail on such a claim, Brashear must show that: (1) Pacira made a representation as to a material fact concerning

Exparel's quality or character; (2) Exparel failed to conform to that representation; (3) Brashear justifiably relied on that representation; and (4) Brashear's reliance on that representation was the direct and proximate cause of her injuries. *Ace Am. Ins. Co. v. Gerling & Assocs., Inc.*, No. 2:19-cv-5627, 2022 WL 4468584, at *5 (S.D. Ohio Sept. 26, 2022) (interpreting the elements of Ohio Rev. Code § 2307.77).

For a false marketing claim to survive a motion to dismiss, district courts³ in this circuit have demanded an alleged misrepresentation that is more than a "broad, all-encompassing statement." *Johnson v. Eisai, Inc.*, 590 F. Supp. 3d 1053, 1060 (N.D. Ohio Mar. 9, 2022) (quoting *Harris v. Eli Lilly & Co.*, No. 4:12-cv-2481, 2012 WL 6732725, at *4 (N.D. Ohio Dec. 28, 2012)). And where "there is no representation," there can be no nonconformance nor any reliance. *Biehl v. B.E.T., Ltd.*, No. 18-3201, 2018 WL 7502930, at *5 (6th Cir. Oct. 17, 2018) (quoting *White v. DePuy, Inc.*, 718 N.E.2d 450, 485 (Ohio Ct. App. 1998)).

So how does Brashear attempt to show a misrepresentation? She alleges that Pacira represented to her that Exparel was "safe and effective for use" as a post-surgical pain reliever. (Doc. 1, #5). But there are two problems with that. First, Brashear appears to be (again) referring to Exparel's labeling itself. *See* 21 U.S.C. § 321(k), (m). But if Brashear believes Pacira's FDA-approved labeling contained misrepresentations, she runs into the same preemption problems as with her other

³ Granted, this Court in *Troyer v. I-Flow Corp.* held that a complaint that similarly lacked any allegation of a specific manufacturer representation nonetheless was sufficiently pled. No. 1:11-cv-45, 2011 WL 2517031, at *4 (S.D. Ohio June 23, 2011). There, however, the complaint set forth facts which allowed the Court to "plausibly infer that a representation was made" and that the product at issue did not conform to it. *Id.* Brashear has alleged no such facts here.

claims. *See Yates*, 808 F.3d at 295. Second, Brashear’s alleged misrepresentation reads like a “broad, all-encompassing statement,” which is insufficient to survive a motion to dismiss. *See Johnson*, 590 F. Supp. 3d at 1060.

In short, Brashear has not plausibly alleged her false marketing claim because she has not alleged a material misrepresentation. True, it is possible Brashear received a misrepresentation *outside* of the label, and such a claim may well evade federal preemption. But her Complaint, as currently presented, lacks sufficient facts to plausibly show that. Therefore, the Court dismisses her claim, but does so without prejudice to allow her to identify a qualifying misrepresentation if she can.

D. Brashear Has Not Plausibly Alleged Supplier Liability Under Ohio Law.

Brashear next says the Defendants bear supplier liability for negligently allowing a dangerous drug to be released to the market and subsequently sold. (Doc. 1, #5). Pacira, the only Defendant so far served, seeks dismissal of this claim by arguing it manufactures Exparel, making it immune from supplier liability. (Doc. 5, #56). And indeed, Pacira cannot be both Exparel’s manufacturer and supplier under Ohio law. *See, e.g., Najib v. Meridian Med. Technologies, Inc.*, 179 F. App’x 257, 262 (6th Cir. 2006) (stating that Ohio Revised Code § 2307.71(15)(b) specifically excludes “manufacturer” from its definition of “supplier”); *Frey v. Novartis Pharms. Corp.*, 642 F. Supp. 2d 787, 795 (S.D. Ohio 2009) (dismissing plaintiff’s claim for relief under supplier liability because the drug’s manufacturer fell outside the statutory definition of “supplier”).

That said, Brashear's Complaint does not actually say which of the three Defendants manufactured Exparel. Rather, Brashear's claims are based on her pleading *in the alternative* that Pacira or two other named defendants are liable as manufacturers *or* suppliers of Exparel. (Doc. 1, #3; Doc. 15, #142). As a result, exactly who she is alleging to have manufactured Exparel, versus who she claims supplied Exparel, is not clear from the Complaint. (Doc. 1, #3, 5). So Pacira's arguments aside, it is plausible from the face of the Complaint that Pacira supplies, rather than manufactures, Exparel. And the same is true for the two unserved defendants—Pacira Pharmaceuticals International, Inc. and Pacira Biosciences, Inc. Thus, the manufacture/supplier distinction cannot alone dispose of Brashear's supplier liability claim.

That leave the plausibility of the claim itself. To succeed on a supplier liability claim under Ohio law, a plaintiff must show that the defendant supplier (1) owed the plaintiff a duty, (2) that the duty was breached, and (3) that the plaintiff's harm proximately resulted from that breach. *Rees v. W.M. Barr & Co., Inc.*, 736 F. App'x 119, 129 (6th Cir. 2018).

Brashear has not plausibly alleged a viable claim under that standard here. Setting aside its legal conclusions, Brashear's Complaint lacks sufficient facts—other than Exparel's alleged defects—to plausibly allege supplier liability. (*See* Doc. 1, #5). And to the extent Brashear bases her supplier liability claim on the “dangerousness” of the Exparel itself, that claim is preempted by federal law for the reasons already discussed.

Again, Brashear could conceivably allege a supplier liability claim against one of the three Defendants in a manner not preempted by federal law. For example, perhaps Pacira negligently contaminated the Exparel while in transit to Brashear, in turn causing Brashear's injury. But Brashear's Complaint contains no allegations—plausible or not—along those lines. The Court therefore grants Pacira's Motion to Dismiss this claim, but again dismisses without prejudice.

E. Ohio Law Precludes Brashear's Claim For Punitive Damages.

Ohio law does not permit punitive damages against a manufacturer of a drug if that drug was “manufactured and labeled . . . in accordance with” FDA guidelines. *Monroe v. Novartis Pharms. Corp.*, 29 F. Supp. 3d 1115, 1129 (S.D. Ohio 2014) (quoting Ohio Rev. Code § 2307.80(C)(1)). While the Ohio statute provides a narrow exception where a plaintiff can show by a preponderance of the evidence that the manufacturer fraudulently withheld from the FDA information related to the plaintiff's alleged harm (*see id.*), the Supreme Court has held that federal law preempts such “state-law fraud-on-the-FDA claims.” *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348–49 (2001) (concluding that the “federal statutory scheme amply empowers the FDA to . . . investigate suspected fraud”).

The Sixth Circuit expanded on *Buckman* and recognized that a plaintiff's state-law fraud claim against the FDA is preempted “unless some federal agency” has already found some fraud on the FDA. *In re Aredia & Zometa Prods. Liab. Litig.*, 352 F. App'x 994, 995 (6th Cir. 2009). Brashear's claim for punitive damages under Ohio law thus only works if the FDA (or some other federal agency) has already discovered

that Pacira made some sort of fraudulent representation about Exparel. *Monroe*, 29 F. Supp. 3d at 1130. Brashear has provided no facts plausibly showing Pacira fraudulently withheld information from the FDA relating to her injury. She also does not say that the FDA or any other federal agency has identified such fraud. As a result, Brashear's claim for punitive damages is preempted.

Because Pacira manufactured Exparel according to FDA requirements,⁴ Pacira is not subject to punitive damages.

F. Brashear Must Show Cause Why The Court Should Not Dismiss Pacira Pharmaceuticals International, Inc., and Pacira Biosciences, Inc., For Failure To Timely Serve.

As previously stated, Brashear only served Pacira Pharmaceuticals, Inc. But Brashear's Complaint also names two other defendants—Pacira Pharmaceuticals International, Inc., and Pacira Biosciences, Inc.

In general, a plaintiff must serve a defendant within 90 days after filing the complaint unless “the plaintiff shows good cause for the failure.” Fed. R. Civ. P. 4(m). Otherwise, a Court may dismiss that defendant “on motion” from a party or on its own after giving notice to the plaintiff. *Id*; see also *Byrd v. Stone*, 94 F.3d 217, 219 (6th Cir. 1996) (explaining that the Federal Rules of Civil Procedure require dismissal without a showing of good cause to justify the failure to effect timely service). Thus, after Brashear filed her Complaint on November 8, 2021, she needed to serve the two

⁴ The FDA initially approved Pacira's new drug application in 2011. In 2018, the FDA approved Exparel for use as a post-operative nerve block to provide pain relief after shoulder surgeries. (Doc. 5, #38, 39).

defendants within ninety days or request an extension to do so. Now almost a year and a half later, Brashear has done neither.

The Sixth Circuit prefers that this Court give Brashear “notice and an opportunity to perfect service.” *Pullen v. Broughton*, 2023 WL 2384438, at *5 (S.D. Ohio Mar. 7, 2023) (quoting *Wesley v. Cuyahoga Cnty. Sheriff’s Dep’t*, No. 1:19-cv-1232, 2021 WL 1895007, at *3 (N.D. Ohio Mar. 18, 2021)). Therefore, the Court **ORDERS** Brashear to **SHOW CAUSE**, no later than May 12, 2023, why the Court should not dismiss this action as against Pacira Pharmaceuticals International, Inc., and Pacira Biosciences, Inc., without prejudice for failure to effect service, or in the alternative explain why the Court should allow an extension of time to perfect such service.

CONCLUSION

The main issue here was whether Pacira could “independently do under federal law” what Brashear’s state-law claims required of it. Brashear has not provided sufficient facts showing that Pacira *could*. Because federal regulations preempt certain state law product liability claims, the Court **GRANTS** Pacira’s Motion to Dismiss (Doc. 5) as to Brashear’s design defect, failure-to-warn, and punitive damages claims and **DISMISSES** those claims **WITH PREJUDICE**. The Court further **GRANTS** Pacira’s Motion to Dismiss (Doc. 5) as to Brashear’s false marketing and supplier liability claims and **DISMISSES** those claims **WITHOUT PREJUDICE**.

Separately, the Court **ORDERS** Brashear to **SHOW CAUSE**, no later than May 12, 2023, why the Court should not dismiss this action as against Pacira Pharmaceuticals International, Inc., and Pacira Biosciences, Inc., without prejudice for failure to effect service, or in the alternative explain why the Court should allow an extension of time to perfect service on those defendants. Failure to comply with this Order may result in dismissal of those two defendants.

SO ORDERED.

April 25, 2023

DATE



DOUGLAS R. COLE
UNITED STATES DISTRICT JUDGE